JJM-85

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: PAUL T. JACOBS ET AL.

Serial No.: 08/120,303 Art Unit: 1809

Filed : SEPTEMBER 13, 1993 Examiner: J. WARDEN

For : METHOD AND DEVICE FOR VAPOR STERILIZATION ARTICLES HAVING LUMENS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

December 16, 1994
(Date of Deposit)

Joseph F. Shirtz
Name of applicant, assignee, or Registered Representative

(Signature)

December 16, 1994
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

APPEAL BRIEF

Dear Sir:

Further to the Notice of Appeal filed in the above-identified application, Applicants submit Appellants' Brief pursuant to 37 CFR §1.192.

1) STATUS OF THE CLAIMS

The present application is a divisional application. Claims 1-10 were allowed in the prior case and have therefore been cancelled in the present application. Claims 11 and 17-20 have been rejected and Claims 12-16, 21 and 22 have been allowed (as indicated by the Advisory Action dated July 21, 1994).

2) **STATUS OF AMENDMENTS**

An Amendment after final rejection was filed on June 17, 1994. By Advisory Action dated July 21, 1994, the Amendment was indicated as to be entered upon filing of Appellants' Brief.

3) **SUMMARY OF THE INVENTION**

In many vapor sterilization processes (for purposes of this application, vapor sterilization processes include most chemical sterilization processes as well as plasma sterilization processes) it has been found to be extremely difficult to sterilize the internal portions of long lumens. That is, in medical devices, the types of lumens that are present in scopes of various types. The advent of less invasive surgery has increased the use of scopes as well as medical devices having long bores. During most chemical sterilization processes, the sterilizer is pumped down or evacuated at the beginning or during the course of the sterilization process. It has been found that by providing a source of chemical sterilant at one end of the lumen, this pumping down draws the chemical sterilant through the internal bore of the lumen, thus sterilizing the internal bore. Without this supply of chemical sterilant (antimicrobial solution), it is difficult to force the sterilant into the lumens once in the gaseous or vapor phase.

The present invention revolves around a device for providing a source of antimicrobial solution to the internal bore of these lumens. For example, referring to Figure 1, the device may attach through insertion of the lumen 12 into a tightly fitting opening 18. The solution source is thus sealed to one end of the lumen. The source may either be contained within a bag or vial-like device immediately attached to the lumen, or within a secondary vial 14 as shown in Figure 1. The alternative embodiment of Figure 2 is a solid one-piece unit in which the source of antimicrobial vapor is indicated as 42. In this device a flexible bore tightly closes around the end of the lumen thus attaching the device to the lumen and providing communication between the internal bore of the lumen and the space within the device 30.

The devices must be small enough to be received within the sterilizer and are preferably small enough to be received within sterilization trays which are inserted into a sterilizer. The description of the preferred embodiment depicted in Figure 1 is present in the specification on pages 10 and 11. Therein it is described that the means for connecting the vessel 14 to the end of the tube comprises and expandable sheath 16, one end of which is securely attached to the vessel and the other end of which comprises an elastic ring 18 making a releasable attachment about the end of the tube. The alternative embodiment of Figure 2 is described particularly at the bottom of page 11 and the top of page 12 of the specification. In this device the means for connecting the vessel 34 to the end of the tubular instrument comprises a bushing 36 disposed within the end of the vessel. The bushing may comprise a series of rings 38 and 40 which are formed of inwardly-extending plastic flaps which define flexible apertures 32 to receive the tubular instrument.

4) ISSUES

A) Whether Claim 17 is indefinite under 35 USC §112 second paragraph in requiring the device be closed to the ambient atmosphere except through a first opening when a second opening having a vessel attached is present.

B) Whether Claims 11 and 18-20 are obvious under 35 USC §103 in view of the reference to Wyka.

5) GROUPING OF THE CLAIMS

Claims 11, 18 and 19 stand as a first group. Claim 17 stands as a second group, and Claim 20 stands as a third separate group.

6) **ARGUMENT**

A) **35 USC §112 Rejection of Claim 17**

Initially, Claim 17 has been rejected under 35 USC §112 as being indefinite for being in improper dependent form. The rejection maintained that the subject matter of Claim 17 failed to properly limit the subject matter of Claim 11. Claim 11 has been incorporated into Claim 17 by rewriting Claim 17 in independent form. However the Examiner still maintains the rejection.

The specific language which the rejection is based upon in the claims is the limitation that "...said vessel being closed to the ambient atmosphere except through such opening...". The Examiner states that this language is inconsistent with the main portion of Claim 17 which states "...wherein said vessel includes a second opening for releasably attaching a cartridge containing said known quantity of antimicrobial solution." This specific claim relates to the structures shown in Figure 1 and Figure 2A wherein there is an adaptor device which attaches to the end of a lumen and a source of antimicrobial solution which attaches to one end of the adaptor device opposite to the lumen.

Referring to the claim language, the first limitation described above is a specific limitation as to the vessel being closed to the ambient atmosphere except through a first opening. Referencing the figures, it is easily seen that the adaptor is still only open to the ambient atmosphere through the lumen 12 in Figure 1 and through the opening 32 shown in Figure 2A. The second opening opposite these portions is the opening which communicates with a separate vial indicated as 14 in Figure 1 and 47 in Figure 2A which vial contains the antimicrobial solution. It is apparent that the adaptor remains closed to the ambient atmosphere except through the first opening. Therefore, the language is consistent and very descriptive of the device shown in these figures. A first opening is open to the ambient atmosphere through the lumen and a second opening receives a vessel carrying an antimicrobial solution or source of antimicrobial vapor. Thus, in use, the adaptor is attached to a lumen which is then placed within a sterilizing

chamber. During pump-down (evacuation) of the sterilization chamber, the ambient atmosphere is at a reduced pressure. The source of antimicrobial vapor within the second vessel sublimates or evaporates to provide an antimicrobial vapor. The reduction in the pressure in the ambient atmosphere causes this vapor to pass through the lumen in order to move to the area of lower pressure thus providing a source of antimicrobial vapor for the internal portion of a lumen of a medical device. The vessel remains closed to the ambient atmosphere except through the first opening because the vessel attached to the second opening does not permit communication with the ambient atmosphere. Although there is a second opening, that opening is not providing communication to the ambient atmosphere, therefore, both limitations of the claim are consistent and definite. For these reasons, the rejection of Claim 17 under 35 USC §112 should be reversed.

B) 35 USC §103 Rejections

1. 35 USC §103 Rejection of Claims 11, 18 and 19

Claim 11 and those claims immediately dependent thereon have been rejected under 35 USC §103 as being unpatentable over Wyka, U.S. Patent No. 3,371,985, entitled "Vaporizer Device". Wyka describes a disinfectant crystal vaporizing device which made up of a hollow cylinder indicated generally by the numeral 1 in Figure 1 which has attached thereto a supply hose 6 and two exit hoses 10 and 12 for attachment to a mattress or the like. In use, the cylinder 1 is filled with disinfecting crystals and air is forced through the supply hose 6 via the vacuum cleaner designated by the numeral 2. The supply hose 6 is attached to the exhaust of the vacuum cleaner thus providing forced air through the cylinder 1 and across the disinfectant crystals. The air containing gaseous disinfectant from the sublimation of the crystals then passes through hoses 10 and 12 into a mattress indicated by the numeral 4. The vacuum side of vacuum cleaner 2 is attached to an opposite side of the mattress 4 via hoses 20, 24 and 26.

Claim 11 of the present application calls for a device for delivering antimicrobial vapor to the lumen of an article during solution vapor sterilization. Clearly, the Wyka device is not usable during solution vapor sterilization as it requires a large apparatus such as a vacuum cleaner and numerous hoses to be attached to it. Furthermore, Claim 11 specifically calls for the device to include a vessel which is "closed to the ambient atmosphere" except through a particular opening which is attached to the lumen of the device to be sterilized. The Wyka device is open not only through the exit hoses 10 and 12, but also through its supply hose 6 to the ambient atmosphere. Granted the atmosphere must pass through the vacuum cleaner first, but this is not sealed and therefore the ambient atmosphere enters the Wyka device through the hose 6. Thus, it must be open both at its supply end through hose 6 and exit end through hoses 10 and 12.

The device of Wyka requires the use of the vacuum cleaner 2 in order to provide the impetus to circulate the vaporized disinfectant. Contrary to this, the specific structure recited in Claim 11 calling for the vessel to be closed to the ambient atmosphere except through an opening which is attached to the lumen of a device to be sterilized requires that the impetus for the flow of sterilizing vapor through the lumen is the pump-down of the ambient atmosphere which normally occurs in vapor sterilization processes. This pump-down causes the antimicrobial solution to vaporize and pass through the lumen in order to provide equilibrium between the pressure within the vessel and that outside of the lumen. Thus, there is no requirement for an external mechanical force such as the vacuum cleaner provided for in Wyka.

It is accepted that the sublimation of a solid substance to form a sterilizing vapor and the vaporization of the antimicrobial liquid called for in Claim 11 are equivalents. However, the solid crystals of the Wyka reference are not in a predetermined quantity according to any standard in the reference. This may be because the Wyka reference is merely directed at disinfecting mattresses versus the applicability of the present

invention to sterilizing processes. In a sterilizing process great lengths are gone through to assure that the process is complete and sufficient chemical sterilant is available to provide a sterility assurance level which may be required to be as high as one chance in one million that a known microbe would survive. Sterilization has several different definitions, however, they all require a significant amount of kill of sporicidal entities. Disinfection merely requires the reduction of pathogens. Therefore it is unnecessary in a disinfecting process to know the quantity of disinfecting vapor which is available to the process. However, in a sterilizing process the supply, presence and concentration of the sterilizing substance is critical. Therefore, the Wyka reference fails to meet the final limitation of the claim requiring a known quantity of the antimicrobial substance.

For the above-described reasons it is respectfully submitted that Claim 11 and all of the claims dependent thereon are fully allowable over the Wyka reference. Reversal of the Examiner's rejection is respectfully requested.

2. **35 USC §103 Rejection of Claim 20**

Claim 20 has been rejected over the Wyka reference as applied against Claim 12 above. Claim 20 calls for a device for enhancing solution vapor sterilization of medical instruments. Claim 20 is particularly directed to a device which, in actuality, delivers an additional dose of antimicrobial vapor to the lumen of a medical device during a sterilization process.

In a chemical sterilizing process the sterilizer chamber is normally pumped down to a very low pressure. After pump-down, a chemical sterilant normally in vapor form is introduced into the chamber in order to supply the lethal atmosphere for sterilizing the instruments. The device of Claim 20, however, enhances this process by providing an additional dose of the chemical sterilant in a separate vessel which is attached to the lumen of a medical device. During pump-down, the solution (or solid as provided in the Wyka reference which would then sublimate

to provide the chemical sterilant) acts as a source of chemical sterilant. The reduction in pressure in the ambient atmosphere causes the sterilant to vaporize and pass through the lumen of the medical device in order to retain the equilibrium of pressure necessary within the vessel.

Claim 20 specifically calls for means for connecting a vessel to the end of a lumen to provide antimicrobial vapor directly to the lumen during solution vapor sterilization. The Wyka reference provides no structure or description of a function of the Wyka device which could provide these limitations. The Wyka reference is a self-contained disinfecting apparatus not for use within a sterilization chamber. It does not in any way enhance sterilization and, in fact, does not provide sterilization, but merely disinfects. In the Wyka reference it is necessary to provide a vacuum cleaner 2 in order to power the flow of atmosphere through the cartridge 1 to provide the vaporized disinfectant to a mattress 4. The vacuum side of the vacuum cleaner is attached to the opposite side of the mattress in order to pull that very air or atmosphere back into the device for recirculation. Thus, the Wyka device cannot be said to be providing enhanced vapor sterilization of medical devices as there is no sterilization occurring and there is no enhancement of sterilization occurring. The Wyka reference describes a completely self-contained device and, if properly balanced, would not enhance any vapor sterilization occurring outside of the device.

Similarly to the reasoning provided above, the Wyka reference also fails on many of the structural elements of Claim 20. For example, Claim 20 specifically calls for means for connecting a vessel to the end of a lumen to provide antimicrobial vapor directly to the lumen. The device of Wyka is not attached to any lumen. The device has permanent hoses attached at 10 and 12, however, these are attached to the sides of a mattress. The mattress is the device being treated in the Wyka reference. The mattress does not contain any lumens therefore the Wyka reference

cannot be said to teach a device having means for connecting a vessel to a lumen.

Furthermore, Claim 20 specifically calls for the device to be sealed from the ambient atmosphere except through the described means for connecting. Wyka provides a cartridge 1 which is open both through hose 6 via a vacuum cleaner and through hoses 10 and 12. Thus, the cartridge 1 is not limited to being open to the ambient atmosphere only through its exhaust side (hoses 10 and 12), but is also open to the ambient atmosphere through hose 6 via the vacuum cleaner 2. This is because the Wyka reference requires external mechanical motivation of the atmosphere across the crystals in order to force it into the mattress. The device of the present invention, however, as claimed in Claim 20 enhances solution vapor sterilization without the requirement of such external forces being exerted upon the atmosphere in order to force the atmosphere across a supply of vaporized sterilant and thereafter through a lumen.

For these reasons it is respectfully submitted that Claim 20 is fully allowable over the Wyka reference.

For the above-described reasons, it is respectfully submitted that Claim 17 is fully definite under the standards of 35 USC §112 and that Claims 11 and 18-20 are fully allowable over the Wyka reference. Reversal of the Examiner's rejection is respectfully requested.

Respectfully submitted.

Joseph F. Shirtz
Attorney for Applicants
Reg. No. 31,880

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2812
December 16, 1994
JJM85.BRF

APPENDIX

Claims

11. A device for delivering antimicrobial vapor to the lumen of an article during solution vapor sterilization, said device comprising a vessel for containing an antimicrobial solution and having an opening therein, and means for connecting said opening of said vessel to said lumen said vessel being closed to the ambient atmosphere except through such opening said vessel containing a known quantity of antimicrobial solution for vapor formation.

17. A device for delivering antimicrobial vapor to the lumen of an article during solution vapor sterilization, said device comprising a vessel for containing an antimicrobial solution and having an opening therein, and means for connecting said opening of said vessel to said lumen said vessel being closed to the ambient atmosphere except through such opening said vessel containing a known quantity of antimicrobial solution for vapor formation wherein said vessel includes a second opening for releasably attaching a cartridge containing said known quantity of antimicrobial solution.

18. The device of Claim 11 wherein said vessel contains a porous absorbent substrate for containing said antimicrobial solution.

19. The device of Claim 11 wherein the vessel has means for attaching a removable closure cap to the opening thereof.

20. A device for enhancing solution vapor sterilization of the lumen of a medical instrument, said device comprising a vessel for containing an antimicrobial solution, and means for connecting said vessel to the end of said lumen to provide antimicrobial vapor

directly to the lumen during the solution vapor sterilization said device being sealed from the ambient atmosphere except through said means for connecting and containing a known quantity of antimicrobial solution.